

**REMARKS**

Applicants submit that the amendments made herein are fully supported in the present specification as filed and add no new matter. Entry of the present amendment is respectfully requested.

In the alternative, if the Examiner continues with the rejections of the present application, it is respectfully requested that the present Amendment be entered for purposes of an Appeal. The Amendment reduces the issues on appeal by reducing the number of claims and/or overcoming the rejections under 35 U.S.C. § 112, first paragraph. Thus, the issues on appeal would be reduced.

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims and the following remarks.

Applicants note that an Interview with the Examiner before the filing of the present reply was requested. However, the Examiner did not grant the Interview.

***Status of the Claims***

In the present Amendment, claims 1, 3, 5, 24, 25, 27 and 28 have been canceled without prejudice or disclaimer of the subject matter contained therein. Also, claims 7, 13-16 and 26 have been amended. It is worth noting that claim 23 is the only independent claim pending. This makes claims 7-16 and 23 and 26 as pending in the present application.

No new matter is introduced with these claim amendments. Many of the claims have been amended to depend on claim 23.

Based upon the above considerations, entry of the present amendment is respectfully requested.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

***Issues under 35 U.S.C. § 112, First Paragraph***

Claim 1 stands rejected as failing to comply with the requirements of the first paragraph of 35 U.S.C. § 112. See Office Action, paragraph 3, page 2.

Further, claims 1, 3, 5, 24 and 25 stand rejected as failing to comply with the requirements of the first paragraph of 35 U.S.C. § 112. See Office Action, paragraph 3, page 2.

Also, claims 26-28 stand rejected as failing to comply with the requirements of the first paragraph of 35 U.S.C. § 112. See Office Action, paragraphs 4-5, pages 2-4.

Regarding the first two rejections, the disputed claims have been canceled thereby rendering these rejections moot.

Regarding the enablement rejection of claims 26-28, Applicants respectfully traverse in that claims 27-28 have been canceled, and claim 26 now depends on claim 23 which is not at issue. Thus, this rejection has also been instantly overcome.

Reconsideration and withdrawal of these rejections are respectfully requested.

***Issues under 35 U.S.C. § 112, Second Paragraph***

Claims 23-25 stand rejected as failing to comply with the requirements of the second paragraph of 35 U.S.C. § 112. See Office Action, page 6 (paragraph 6). Applicants respectfully traverse.

First, claims 24-25 have been canceled thereby rendering the rejection of these claims moot.

Regarding claim 23, the Examiner is rejecting this claim due to the recitation of “substantially” in describing the pattern of Figure 3. Figure 3, also described in paragraph [0082] at page 27 of the original specification, refers to powder X-ray diffraction data.

However, the Examiner cites M.P.E.P. § 2173.05(b)(F) to support this rejection. While this section of the M.P.E.P. refers to terms such as “superior” and “aesthetically pleasing,” this M.P.E.P. subsection does not refer to the term “substantially.” Instead, M.P.E.P. § 2173.05(b)(D) refers to “substantially,” wherein some case law that holds this term to be definite. For instance, Applicants note *In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975).

Furthermore, Applicants respectfully disagree with the Examiner’s rejection since U.S. case law establishes that “substantially” can be a part of the claim language if the term “serves reasonably to describe subject matter so that its scope would be understood by persons in field of invention, and to distinguish the claimed subject matter from the prior art,” and is “warranted by the nature of the invention, in order to accommodate minor variations that may be appropriate to secure the invention.” See *In re Mattison*, *supra*; *Verve LLC v. Crane Cams Inc.*, 65 USPQ2d 1051, 1054 (Fed. Cir. 2002) (wherein the Federal Circuit found that the term “substantially” does

not render the disputed patent claims invalid for indefiniteness, and remanded to the lower court).

Therefore, Applicants respectfully request reconsideration of claim 23 in its recitation of “substantially”, as such language does not render the claim as indefinite since one skilled in the art can determine the scope of the claimed invention in terms of a certain degree. As stated in *Verve LLC*, terms such as “substantially” are used in patents when warranted by the nature of invention in order to accommodate minor variations that may be appropriate to secure invention and may be necessary in order to provide an inventor with the full benefit of an invention. 65 USPQ2d at 1054. That is the case here given the strength of the peaks of the X-ray diffraction data.

Also, the understanding of the scope of “substantially” can be derived from sources outside the specification. As further support of Applicants’ position, herein enclosed is an excerpt (and English translation thereof) from “Advanced Technology, Application and Development of Polymorphic Crystals” (August 2005). As can be seen from Table 4 (page 17), X-ray diffraction data is sufficient in describing a polymorph. IR and solid state NMR can also identify polymorphic crystals. Thus, with Figure 3 being recited in the claim, the state of the art clearly guides the skilled artisan of the proper meaning of “substantially.”

In addition, Applicants note other case law that supports the claim language of, e.g., “substantially equal” and “closely approximate.” See *Andrew Corp. v. Gabriel Elecs. Inc.*, 6 USPQ2d 2010, 2013 (Fed. Cir. 1988). As stated in *Andrew Corp.*, when serving reasonably to describe the claimed subject matter to those of skill in the field of the invention, and to

distinguish the claimed subject matter from the prior art, the term “substantially equal” has been accepted in patent examination and upheld by the courts. 6 USPQ2d at 2012.

Finally, the USPTO has already accepted claim language like “substantially”. For instance, claim 1 of U.S. Patent No. 7,405,216 B2 uses the term “approximately” in describing X-ray powder diffraction data points.

Accordingly, it is respectfully submitted that all of the claims currently pending in this application comply with the requirements of the second paragraph of 35 U.S.C. § 112. Reconsideration and withdrawal of this rejection are respectfully requested.

#### ***Withdrawn Claims***

Applicants also request that product claim 23 is found allowable, then the process claims of making such a novel product should also be allowable. *In re Ochiai*, 37 USPQ2d 1127 (Fed. Cir. 1995). Thus, rejoinder of the method of making claims is respectfully requested.

#### ***Conclusion***

In view of the above amendment, Applicants believe the pending application is in condition for allowance. A Notice of Allowability is respectfully requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eugene T. Perez (Reg. No. 48,501) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: APR 08 2009

Respectfully submitted,

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Attachment: Masakuni Matsuoka, "Advanced Technology, Application and Development of Polymorphic Crystals," cover and p. 17 (August 2005) (3 pages total)

# 結晶多形の最新技術と応用展開

—多形現象の基礎からデータベース情報まで—

*Advanced Technology, Application and  
Development of Polymorphic Crystals*

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*Supervisor Masakuni Mitsuoka*



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シーエムシー出版

## 第1章 結晶と多形一序論

表4 結晶多形の測定法

測定法	得られる情報
X線回折	多形の区別 (粉末法)、空間群の決定 (単結晶法)、パッキング様式、コンフォメーション
熱測定	多形の区別 (融点と相転移)、多形の熱力学的安定性、融解熱・転移熱・溶解熱、結晶化速度
赤外吸収法・ラマン散乱法	多形の区別 (コンフォメーションとパッキング様式)、分子間相互作用
固体核磁気共鳴法	多形の区別 (局所内部環境)
顕微鏡観察	多形の区別 (形態)、褶曲折

## 5 結晶多形の測定法

最後に、結晶多形の測定法を表4にまとめて示す。それぞれに長所があるが、熱測定とX線回折測定、ならびに顕微鏡観察は必須の方法であろう。X線回折に多結晶粉末法と単結晶法があるが、前者が準安定多形を含めて多形現象を概観的に調べる上では有効である。さらに詳細に多形構造を調べるためには、単結晶を用いた構造解析が望まれるが、準安定多形は良質の単結晶を得にくいので限界がある。さらに微視的な情報は、赤外吸収法・ラマン散乱法・核磁気共鳴法で得られる。

ちなみに、本章の冒頭で薬剤結晶の多形が特許がらみの技術的問題として浮上していることを言及したが、すでに欧米では多形をめぐる特許紛争が生じている。その場合に、表4に示した測定法で得られた多形構造を証明する実験データの信頼性も、法廷で争論論争として争われることを指摘したい。

## 文 献

- 1) X線構造解析, 早稲田嘉夫, 松原英一郎, 内田老鶴舎 (1998)
- 2) 松岡正邦, 結晶化学, 培風館 (2002)
- 3) 佐藤清隆, 小林雅通, 脂質の構造とダイナミクス, 共立出版 (1992)
- 4) L. Yu, *et al.*, *J. Am. Chem. Soc.*, 122, 585 (2000)
- 5) J. Bernstein, *Polymorphism in Molecular Crystals*, Oxford Science Publications, Oxford, (2002)
- 6) S. R. Vippagunta, H. G. Brittain, D. J. W. Grant, *Adv. Drug Delivery rev.*, 48, 3 (2001)
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Table 4 Measurement Method of Polymorphic Crystals

Method	Obtainable Information
X-ray diffraction	Distinction of polymorph (powder), Determination of space group (single crystal), Packing, Conformation
Thermal measurement	Distinction of polymorph (melting point and phase transition), Thermodynamic stability of polymorph, Melting heat, Transition heat, Dissolution heat, Crystallization speed
Infrared absorption spectroscopy / Raman scattering spectroscopy	Distinction of polymorph (conformation and packing), Intermolecular interaction
Solid state nuclear magnetic resonance	Distinction of polymorph (local internal magnetic field)
Microscopic observation	Distinction of polymorph (morphology), Birefringence